Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Saline Nasal Solution

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This draft proposal contains monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
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Monograph proposed for inclusion	IP Addendum 2024
Tentative effective date of monograph	July, 2024
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Draft revision published on IPC website for public comments	-
Further follow-up action as required.	

Saline Nasal Solution

Sodium Chloride Nasal Solution; Sodium Chloride Nasal Drop; Sodium Chloride Nasal Spray.

Sodium Chloride Nasal Solution is a solution of Sodium Chloride in Purified Water.

Sodium Chloride Nasal Solution contains not less than 97.0 per cent and not more than 105.0 per cent of the stated amount of the Sodium Chloride, NaCl.

Usual strengths. 0.65 per cent w/v; 0.74 per cent w/v.

Identification

It gives the reaction of sodium salts and reaction (A) of chlorides (2.3.1).

Tests

pH (2.4.24). 6.5 to 7.5.

Microbial contamination (2.2.9). Total aerobic viable count is not more than 10^2 CFU per ml and total combined mold and yeasts count is not more than 10 CFU per ml and 1 ml is free from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Burkholderia cepacia*.

Other tests. Comply with the tests stated under Nasal Preparations.

Assay. To 20.0 ml add 50.0 ml of *0.1 M silver nitrate*, 5 ml of *2 M nitric acid* and 2 ml of *dibutyl phthalate*. Shake well and titrate the excess of silver nitrate with *0.1 M ammonium thiocyanate* using 2 ml of *ferric ammonium sulphate* solution as indicator until a reddish yellow colour is produced. Carry out a blank titration.

1 ml of *0.1 M silver nitrate* is equivalent to 0.005844 g of NaCl.

Storage. Store at a temperature not exceeding 30º.